



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

34136d

WARNING LETTER

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

Certified Mail –
Return Receipt Requested

July 11, 2003

Freeman H. Rose
President and CEO
MagnuVu
2225 Faraday Avenue, Suite F
Carlsbad, CA 92008

WL 44-03

Dear Mr. Rose:

During an inspection of your firm located in Carlsbad, California, from June 5 to 11, 2003, our investigator determined that your firm manufactures a portable magnetic resonance imaging (MRI) system designed to image human extremities. This imaging system is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection disclosed that your device is adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish, maintain and control a quality system that is appropriate for specific devices manufactured [21 CFR 820.5 and 21 CFR 820.20]. Specifically, management with executive responsibility has not ensured that quality system requirements are effectively established and maintained.
2. Failure to control procedures for conducting quality audits and failure to conduct audits to verify that the quality system is effective in fulfilling the quality system objectives [21 CFR 820.22]. Specifically, no quality audits have been conducted since the establishment of your quality system procedures in July 2000.
3. Procedures for identifying training needs have not been followed [21 CFR 820.25(b)]. Specifically, employee training needs were not addressed and training was not documented.

4. Software validation activities for computers or automated data processing systems used as part of production have not been performed or documented [21 CFR 820.70(i)]. Specifically, the Eng MagMRI software used for engineering and servicing of the MagneVu 1000 MRI System has not been validated.
5. Failure to adequately implement complaint handling procedures for receiving, reviewing and evaluating complaints to ensure they are processed in a uniform and timely manner. [21 CFR 820.198(a)(1)]. Specifically, complaints submitted as service requests are not entered into the complaint handling system and reviewed and evaluated to determine whether an investigation is necessary.
6. Procedures for evaluating non-conforming product(s) have not been adequately implemented [21 CFR 820.90(a)]. Specifically, non-conformances identified in the assembly and receiving inspection of the Magne Vu 1000 MRI System were not documented.
7. Records of acceptable suppliers were not maintained [21 CFR 820.50(a)(3)]. Specifically, the results of the audits of your magnet and printed circuit board suppliers were not documented
8. Documents which were not approved were found at a location where they were being used [21 CFR 820.40(a)]. Specifically, the sensor assembly set procedure used in the assembly of the MagneVu 1000 MRI System has not been formally approved through your document control system.
9. Acceptance test results for the MagneVu 1000 MRI System were not adequately documented [21 CFR 820.80 (c) and (d)]. Specifically, final acceptance records for release of the MagneVu 1000 MRI System did not document the results of the acceptance activities or equipment/software used in conducting the tests, and were not signed by the individual who performed the acceptance activities.
10. Procedures for reviewing sampling methods for adequacy were not followed [21 CFR 820.250(b)]. Specifically, established sampling plans were not followed.
11. The Device History Records for the MagneVu 1000 MRI System are not adequate. They do not include the primary identification label and labeling for each device [21 CFR 820.184(e)]. Specifically, 16 of 16 device history records for the MagneVu 1000 MRI System did not include any primary identification label or labeling for the device as part of the file.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the U.S. Food and Drug Administration (FDA). If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

We acknowledge receipt of written response dated June 24, 2003 addressing the observations listed on the form FDA 483 issued to you on June 11, 2003. We have completed our review of your response and have determined that your response does not adequately address our concerns. Your response does not contain sufficient documentation of the supporting activities conducted by your firm to correct the deficiencies disclosed during our inspection.

Your response to this Warning Letter should specify when your internal audits were or will be completed and the results. It should indicate the number of employees that participated in the training activities, the instructors and their qualifications, and the training syllabus or materials used. The response should indicate how far back your reviews went and the outcome of the reviews and any corrective measures undertaken.

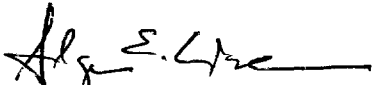
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If you have any questions relating to this letter please contact Senior Compliance Officer,
Dannie E. Rowland at (949) 798-7649.

Please submit your response to:

Acting Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Sincerely,

A handwritten signature in black ink, appearing to read 'Alonza E. Cruse', with a stylized flourish at the end.

Alonza E. Cruse
District Director
Los Angeles District Office

Cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-35
Sacramento, CA 94234-7320